

REMARKS

Claims 1 and 5-42 are pending, with Claims 14-18 and 25-42 previously withdrawn from consideration and Claims 1, 5-13, and 19-24 previously under examination. Applicants request that Claims 14-18, 25-33 and 38-42, previously withdrawn from consideration, be considered in light of claim amendments presented herein. Claims 1, 10, 11, 17, 19, 21, 27-33, and 38-42 are currently amended. Claims 2-4, 34-37, and 43-75 have been cancelled. Thus, Claims 1, 5-33, and 38-42 are currently pending and presented for examination.

Examiner's Interview

Applicants thank Examiner Kolker and Supervisory Patent Examiner Turner for the courtesy extended to Applicant and Applicant's representative during the interview conducted on October 24, 2005. A summary of the substance of the Interview was provided by the Examiner (Interview Summary mailed October 26, 2005).

Request to Consider Claims to Nonelected Species

In the Office Action mailed December 2, 2004, it was noted that, upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species. With respect to Claims 25-33 and 38-42 to nonelected species, Applicants request consideration of these claims as provided by 37 C.F.R. §1.141(a) if generic claims are found allowable.

Claim Rejections

Rejections under 35 U.S.C. §112, first paragraph

Claims 1, 5-13, and 19-24 stand rejected under 35 U.S.C. §112, first paragraph, with respect to diseases other than Alzheimer's disease or ALS-PDC, on grounds that the specification allegedly does not reasonably provide enablement for any other neurological diseases. Applicants respectfully request that Claims 1, 5-13, and 19-24 be reconsidered in light of the claim amendments presented herein, and the rejection of these claims under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. §102

Claims 1, 7-13, and 22-24 stand rejected under 35 U.S.C. §102(b) over Kisby *et al.* (1988, *J Neurosci Meth* 26:45-54), on grounds that Kisby *et al.* allegedly discloses "a method of detecting BMAA in tissue samples from subjects having or at risk of having neurological disorders wherein BMAA is associated with the neurological disorder" (Office Action (OA)

page 6, lines 3-5). It is admitted that Kisby *et al.* teaches detection of BMAA in serum from monkeys treated with BMAA (OA, page 6, lines 5-7).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1052 (Fed. Cir. 1987). Applicants respectfully point out that Claim 1, as amended, recites detecting the presence of a neurotoxin in a human subject by analyzing a tissue sample from the subject to determine the presence of BMAA or a BMAA derivative. Kisby *et al.* does not teach detecting the presence of a neurotoxin in a human subject by analyzing a tissue sample from the subject to determine the presence of BMAA or a BMAA derivative. Therefore, Kisby *et al.* does not anticipate Claims 1, 7-13, and 22-24 the rejection of these claims under 35 U.S.C. §102(b) should be withdrawn.

Rejections under 35 U.S.C. §103

Claims 1, 5, and 6 stand rejected under 35 U.S.C. §103 as unpatentable over Kisby *et al.* (1988, *J Neurosci Meth* 26:45-54), in view of Duncan *et al.* (1990, *Neurology* 40:767-772) and Duncan *et al.* (1992, *J Neuroscience*, 12:1523-1537).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to produce the claimed invention. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See*, MPEP §§ 2142, 2143.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka* 180 USPQ 580 (CCPA 1974). Applicants respectfully point out that Claim 1, as amended, recites detecting the presence of a neurotoxin in a human subject by analyzing a tissue sample from the subject to determine the presence of BMAA or a BMAA derivative. The combination of Kisby *et al.*, disclosing measuring BMAA in cycad seeds and in tissues from monkeys and rats fed with BMAA, with Duncan *et al.* (1990) and Duncan *et al.* (1992), which disclose measuring BMAA levels in cycad flour, does not teach the claimed invention. Therefore, this criterion for establishing a *prima facie* case of obviousness has not been met.

Because criteria for a *prima facie* case of obviousness have not been satisfied, no *prima facie* case of obviousness has been established and therefore, the rejection of Claims 1, 5 and 6 under 35 U.S.C. §103(a) is improper and should be withdrawn.

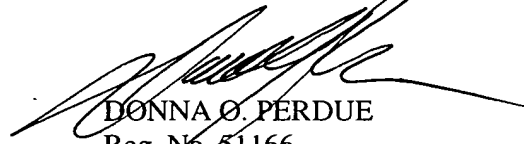
CONCLUSION

Claims 1 and 5-42 are currently pending. Claims 1, 10, 11, 17, 19, 21, 27-33, and 38-42 are currently amended. Claims 2-4, 34-37, and 43-75 have been cancelled. Claims 1, 5-33, and 38-42 are currently under examination. Applicants submit that, in light of the amendments and remarks presented herein, Claims 1, 5-33, and 38-42 are now in condition for allowance.

Applicants believes that fees are due. Please charge any fees associated with the submission of this paper to Deposit Account Number 50-2212. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

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I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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